

**REMARKS**

This paper is filed responsive to the Office Action mailed May 27, 2009. Claims 1-3, 5 and 8-20 are pending in the application. Claims 4 and 6-7 have been canceled. Claims 1-3 and 20 are amended. Claim 21 is new. No new matter is added.

Claim 1 claims a bone cement plug for fitting into the intramedullary canal within a bone to restrict flow of bone cement during surgery that includes:

a sleeve having a longitudinal axis, an outer surface configured to contact the wall of the canal, and inner surfaces configured to define an internal cavity whose diameter decreases from a distal end to a proximal end, whereat the internal cavity communicates with an opening formed in the outer surface, the sleeve being formed from a deformable material and configured to be expanded transversely to contact the surface of the canal;

an expander comprising a shaft having a distal end and a transverse portion that extends radially from the distal end of the shaft, the shaft dimensioned to extend through the opening;  
and

a washer disposed on the shaft, and having a plurality of radially slots formed therein extending from the outside edge of the washer toward the inside edge thereof; and

wherein the expander is movable within the cavity in a direction generally along the longitudinal axis from a distal position to a proximal position, whereat the washer contacts the internal cavity to cause the wall of the sleeve to expand transversely to contact the surface of the canal.

One embodiment of the invention is depicted in Figure 1 below.

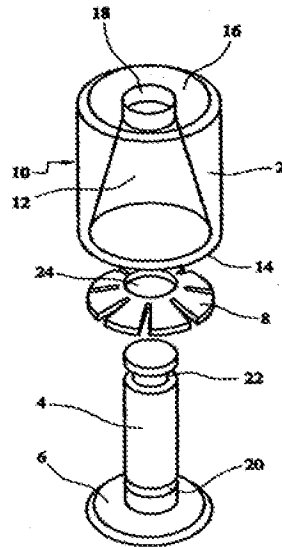
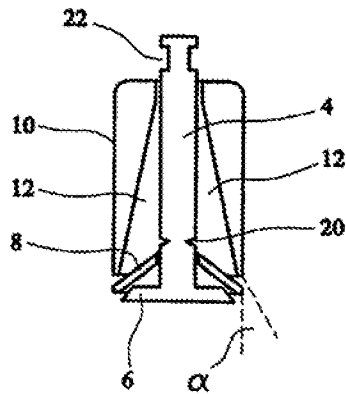


FIG. 1

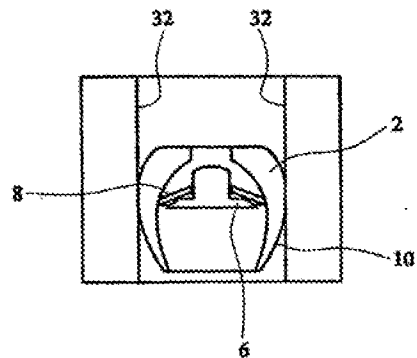
The bone cement plug includes a sleeve 2 having an internal cavity 12 that communicates with an opening 18 at the proximal end 16, an expander comprising a shaft 4 having a distal end and a transverse portion 6 that extends radially from the distal end of the shaft, and a washer 8 disposed on shaft 4. Shaft 4 is dimensioned to extend through opening 18, as shown in Figure 2. Washer 8 has a plurality of radially slots formed therein extending from the outside edge of the washer toward the inside edge.

Figures 2 and 3, below, depict the invention embodiment in use. The expander starts at a distal position in Figure 2.



**FIG. 2**

As is shown in Figure 2, shaft 4 extends through opening 18 in sleeve 2. The device “is fitted to an instrument (not shown) which has a socket in which the shaft can be received. The shaft can be releasably engaged against axial separation by means of grippers which fit into the recess 22 in the shaft.” Paragraph 0034 of U.S. Application Publication No. 2007/0083212. The instrument is then used to insert the plug into the bone canal. Once positioned, “the instrument is then actuated to draw the expander through the sleeve 2, relying on the engagement between grip means on the instrument and the recess on the shaft. This causes the transverse portion 2 of the expander and the washer 8 to be drawn into the cavity 12 within the sleeve.” Paragraph 0035 of U.S. Application Publication No. 2007/0083212. At least at this distal position, the washer is in the conical configuration, as is claimed in claim 2.



**FIG. 3**

As the transverse portion 2 and washer 8 are drawn into the cavity, the reducing diameter of the internal cavity and the action of the transverse portion against the internal cavity, causes the sleeve to be deformed outwardly, to engage the inner surface 32 of the bone canal. Continued drawing of the expander into the sleeve causes the washer to flatten, so that the diameter of washer 8 increases as shown in FIG. 3. Paragraph 0035 of U.S. Application Publication No. 2007/0083212.

Claims 1-3, 8, 12, 13, and 17-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,554,191 (Lahille) in view of U.S. Patent No. 6,123,706 (Lange). Applicants traverse the rejection.

Neither Lahille nor Lange disclose the claimed elements of independent claims 1 or claim 20. As shown in Figure 7 below, Lahille depicts a vertebral cage 3 that includes a two branches 31, 32 linked by a bridge 34. A screw 36 extends through a slot 34 provided between the branches, ***but does not extend through the proximal opening (described as counterbore 332)***. Screw 36 has a head 361 at the proximal end which mates with a screwdriver 5. Member 37 is threaded onto screw 36. See Lahille, col 7:36-45. When the screwdriver is engaged with head 361 and turned, the screw 36 turns thereby screwing into member (or spreader roller) 37. As a result, member 37 moves or travels along the screw toward head 361. As it does so, member 37 acts against the inner surfaces of branches 31, 32 thereby causing branches 31, 32 to spread. Lahille, col 9: 21-27.

Thus, Lahille fails to describe at least the claimed expander limitation of claims 1 and 20, which requires that the expander has a shaft that is dimensioned to extend through the opening in the sleeve, and that the expander is movable within the cavity in a direction generally along the longitudinal axis from a distal position to a proximal position. The screw 36 of Lahille which is alleged to depict the claimed expander is not movable from a distal to proximal direction. ***Screw 36 remains in one place; the member 37 travels along screw 36.*** Further, screw 36 does not extend through counterbore 332. As a result, Lahille fails to describe the limitations of claim 1 and claim 20. Lange is cited for its star shaped washer 52, and does not

describe the claimed limitations. As a result, Applicants submit that the claimed inventions are patentable over Lahille and Lange and request the Examiner to withdraw the rejection with respect to claims 1 and 20.

Nor do Lahille or Lange disclose the elements claimed in claim 2 or 21. As described above, the washer of the inventions claimed in claims 2 and 21 is disposed on the shaft and has a plurality of radially slots formed therein extending from the outside edge of the washer toward the inside edge thereof. Further, the washer has a conical configuration, where the diameter of the washer is approximately equal to the diameter of the transverse portion, and a flattened configuration, where the diameter of the washer is greater than the transverse portion. Neither Lahille, nor Lange describe such a washer. The washer of Lahille, shown as stop washer 363, is welded to the shank 362 to prevent member 37 from demounting when screw 36 is turned. Lahille, col 7:46-49. Washer 363 is not capable of changing its configuration from a conical to a flattened configuration when the expander is moved from a distal to a proximal position. First, as described above, screw 36 does not move from a distal to a proximal position. Second, washer 363 is not taught to change configuration and neither is washer 52 of Lange. As a result, Applicants submit that the claimed inventions are patentable over Lahille and Lange and request the Examiner to withdraw the rejection with respect to claim 2 and newly added claim 21.

Claim 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lahille in view of Lange, further in view of U.S. Pat. No. 6,669,733 (Spierings). Claims 9 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lahille in view of Lange, as shown in claim 1, further in view of U.S. Patent No. 7,156,880 (Evans). Claims 10, 11, 14, and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lahille in view of Lange. Applicant traverses the rejections, and submits that claims 5, 9-11, 14, 15 and 16 are patentable at least because they ultimately depend from independent claim 1. Applicants request that the Examiner withdraw the rejections.

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Respectfully submitted,

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